

**K193107 TriSalus Infusion System**Dec 3, 2019  
25 days to decisionK193107 · Product code: **KRA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k193107/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Catheter, Continuous Flush (KRA)   |
| Date received         | Nov 8, 2019                        |
| Decision date         | Dec 3, 2019                        |
| Days to decision      | 25 days                            |
| Third-party review    | Yes                                |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Trisalus Life Sciences</b>         |
| Location       | Westminster, CO, US                   |
| Contact        | Patrick McCain                        |
| 510(k) history | 3 submissions · 3 cleared · 2019-2023 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193107/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 24, 2026